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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,258	11/07/2008	Gabriele Pretzer	207,849	4679

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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
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1633

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09/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,258	Applicant(s) PRETZER ET AL.
	Examiner KELAGINAMANE T. HIRIYANNA	Art Unit 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372 for claims 1-24 in the Application filed on 11/07/2008.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions as claimed are classified into following groups:

I. Claims 1-4 drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding a mannose-specific adhesin polypeptide wherein nucleotide sequence is selected from the (i) nucleotide sequence that encodes amino acid sequence that has at least 60% sequence identity with the amino acid sequence of SEQ ID NO:1 or (ii) a nucleotide sequence whose complementary strand hybridizes to nucleic acid molecule of (i) or a (iii) nucleotide sequence, the sequence of which differs from the sequence of a nucleic acid molecule of (ii) due to degeneracy of the genetic code and further drawn to fragment or variant of said nucleic acid molecules that encode a fragment or variant polypeptide that is capable of binding mannose. The invention is further drawn to a vector comprising nucleic acid molecules described above.

II Claims 1-4 drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding a mannose-specific adhesin polypeptide wherein nucleotide sequence is selected from the (i) nucleotide sequence that encodes amino acid sequence that has at least 60% sequence identity with the amino acid sequence of SEQ ID NO:2 or (ii) a nucleotide sequence whose complementary strand hybridizes to nucleic acid molecule of (i) or a (iii) nucleotide sequence, the sequence of which

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differs from the sequence of a nucleic acid molecule of (ii) due to degeneracy of the genetic code and further drawn to fragment or variant of said nucleic acid molecules that encode a fragment or variant polypeptide that is capable of binding mannose. The invention is further drawn to a vector comprising nucleic acid molecules described above.

III Claims 5--9 drawn to a host cell comprising nucleic acid molecule of invention I or II as above.

IV Claims 10-12 and 23-24 drawn to an isolated polypeptide having an amino acid that has at least 60% sequence identity with the amino acid sequence of SEQ ID NO:1 and to a composition of said isolated polypeptide..

V Claims 13-15 drawn to a method of producing an isolated polypeptide having an amino acid that has at least 60% sequence identity with the amino acid sequence of SEQ ID NO:1 and to a composition of said isolated polypeptide .

VI Claims 16-17 and 21-22 drawn to a method of treating or preventing a bacterial infection comprising administering the patient in need of such treatment an effective amount of a composition of a host cell comprising nucleic acid molecule of invention I or II as above.

VII Claims 18-19 drawn to use of a host cell comprising nucleic acid molecule of inventions I or II as above or an isolated polypeptide having an amino acid that has at least 60% sequence identity with the amino acid sequence of SEQ ID NO:1.

VIII Claims 20 is drawn to a method of determining whether a bacterium has the ability to bind a mannose.

The inventions listed above as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions listed above as Groups I-VIII lack unity of invention because even though the inventions of these groups require the technical feature of 'nucleic acids encoding amino acid sequence of 60% identity to SEQ ID NO:1 or NO:2', this technical feature

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is not a special technical feature as it does not make a contribution over the prior art in view of for example i) Databse EMBI cell surface protein (dated 06/01/2003), XP002297276 (from document of record) describing 100% identity to SEQ ID NO:1 and Kleerebezem et al (2003, PNAS USA 100:190-195; art of record) who teaches sequences that is 100% identical to SEQ ID NO:2). The invention as whole thus lacks unity under PCT rules and hence a restriction as indicated above is proper. The structure of specific method steps and compositions of the above inventions and their mode of operation, and the effects evaluated in each of the above invention are distinct and different from the other. Therefore, a search and examination for the patentability of the above inventive groups together would generate an undue search burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between sub-combinations usable together. Where applicant elects a sub-combination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable sub-combination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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This application contains claims directed to the following patentably distinct species:
With any of the invention Groups (I, II, II, IV, V, VI VII or VIII) elected from above.

- (a). Applicant is required to choose a single species of the corresponding nucleic acid molecule encoding said mannose binding polypeptide and or the corresponding amino acid sequences encoded by said nucleic acid molecule recited in claims 1 & 2 .

The species are independent because they are structurally distinct.

This application contains claims directed to the following patentably distinct species:
Should Applicant elect the invention Group III from above.

- (a). Applicant is further required to choose a single species of host cell among the host cell recited as a Markush group in claim 7.

The species are independent because they are structurally and clinically distinct.

This application contains claims directed to the following patentably distinct species:
Should Applicant elect the invention Group IV from above.

- (a). Applicant is further required to choose a single species of bacterial infection among the bacterial infections recited in claim 23.

The species are independent because they are structurally and clinically distinct.

This application contains claims directed to the following patentably distinct species:
Should Applicant elect the invention Group VI from above.

- (a). Applicant is further required to choose a single species of bacterial infection among the bacterial infections recited in claim 16.

The species are independent because they are structurally and clinically distinct.

This application contains claims directed to the following patentably distinct species:
Should Applicant elect the invention Group VII from above.

- (a). Applicant is further required to choose a single species of bacterial infection among the bacterial infections recited in claim 18.

The species are independent because they are structurally and clinically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/

Primary Examiner, Art Unit 1633